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Eddie E. Scot	·	. MUMMERT, STEPHANIE KANE		
Assistant Laboratory Counsel Lawrence Livermore National Laboratory P.O. Box 808, L-703			ART UNIT	PAPER NUMBER
			1637	
Livermore, CA	94551 .		DATE MAILED: 09/19/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

N						
Office Action Summary		Application No.	Applicant(s)			
		10/718,856 MARIELLA ET AL.				
		Examiner	Art Unit			
		Stephanie K. Mummert	1637			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)	) Responsive to communication(s) filed on					
2a) <u></u> ☐	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims	·				
4) Claim(s) 1-62 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-9,11-16,19-30,32-37,41-51 and 53-58 is/are rejected.  7) Claim(s) 10,17-18,31,38-40,52 and 59-60 is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	on Papers					
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Example 1.	epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
Priority u	ınder 35 U.S.C. § 119		·			
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa				

#### **DETAILED ACTION**

## **Priority**

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged.

### Information Disclosure Statement

- 2. The information disclosure statement (IDS) submitted on November 21, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.
- 3. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As currently written, the limitation of claim 3 is a repetition of the limitation of claim 1.

# Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3, 7-9, 21-22, 24, 28-30, 42-43, 45 and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 3, 22, 24, 43 and 45, the term "using a complementary sequence as a template and a ligase" is vague and indefinite. As written, it seems as though the complementary sequence is being used as both a template and as a ligase. If it is the intention to use a ligase and a complementary sequence as a template, a suggested correction would be to move the term "a ligase" to the start of the phrase to read instead "using a ligase and a complementary sequence as a template."

Regarding claims 7-9, 28-30 and 49-51, it is vague and indefinite what is meant by the term "at said surface" as recited in the referenced claim(s). Is the term "at" intended to imply that the item (e.g., template, linker, dsDNA) is to be attached to the surface? How is the item attached? Is the term intended to suggest that the item is located near the surface without attachment? How near to the surface?

Regarding claims 21 and 42, the term "making" is vague and indefinite. It appears to be used interchangeably with the term "constructing" used in claim 1; however, the two terms are not necessarily equivalent and consistency of terminology should be maintained.

Further regarding claims 21 and 42, the term "PCR-ready" is vague and indefinite. It is unclear what is meant by the term and what would distinguish DNA as PCR-ready from DNA that is not PCR-ready.

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## Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 7. Claims 1-4, 11, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Strizhov et al. (US Patent 6,110,668; August 2000). Strizhov teaches a method of gene synthesis that utilizes a combination of enzymatic and chemical synthesis (Abstract).

With regard to claim 1 and 3, Strizhov teaches a method of constructing polynucleotides, comprising the steps of: ligating the strands of DNA using a complementary sequence as a template and a ligase (Figure 1, where template directed ligation is carried out with *Pfu* ligase; see also col. 2, lines 45-67 to col. 3, lines 1-40).

With regard to claim 2, Strizhov teaches a method of constructing polynucleotides wherein said step of ligating utilizes a complementary sequence as a template (Figure 1, where template directed ligation is carried out with *Pfu* ligase; see specifically, col. 2, lines 52-65).

With regard to claim 4, Strizhov teaches a method of constructing polynucleotides wherein said step of ligating utilizes a ligase (Figure 1, where template directed ligation is carried out with *Pfu* ligase; see also col. 2, lines 45-67 to col. 3, lines 1-40).

With regard to claim 11, Strizhov teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase joining two strands of DNA (Figure 1, where template directed ligation is carried out with *Pfu* ligase; see specifically, col. 2, lines 52-65).

With regard to claim 14, Strizhov teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA (Figure 1, where template directed ligation is carried out with *Pfu* ligase; see specifically, col. 2, lines 52-65).

With regard to claim 15, Strizhov teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA using a second complementary strand (Figure 1, where template directed ligation is carried out with *Pfu* ligase; see specifically, col. 2, lines 52-65).

With regard to claim 16, Strizhov teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA using a second complementary strand as a template (Figure 1, where template directed ligation is carried out with *Pfu* ligase; see specifically, col. 2, lines 52-65).

8. Claims 1-4, 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sgaramella et al. (1970, PNAS, vol. 67, no. 3, pp. 1468-1475). Sgaramella teaches the joining reaction catalyzed by T4 Ligase (Abstract).

With regard to claims 1 and 3, Sgaramella teaches a method of constructing polynucleotides, comprising the steps of: ligating the strands of DNA using a complementary sequence as a template and a ligase (p. 1469, lines 3-8, where icosanucleotide formed between segments 1 and 4 were used as a template for joining segments 2 and 3, see Figure 1; see also p. 1470, materials and methods, where T4-polynucleotide ligase were used).

With regard to claim 2, Sgaramella teaches a method of constructing polynucleotides wherein said step of ligating utilizes a complementary sequence as a template (p. 1469, lines 3-8, where icosanucleotide formed between segments 1 and 4 were used as a template for joining segments 2 and 3, see Figure 1; see also p. 1470, materials and methods, where T4-polynucleotide ligase was used).

With regard to claim 4, Sgaramella teaches a method of constructing polynucleotides wherein said step of ligating utilizes a ligase (see p. 1470, materials and methods heading, where T4-polynucleotide ligase was used).

With regard to claim 11, Sgaramella teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase joining two strands of DNA (Figure 1).

With regard to claim 12 and 13, Sgaramella teaches a method of constructing polynucleotides wherein said step of ligating utilizes sticky-end or blunt-end ligase

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joining two strands of DNA (Figure 1, where overhanging ends are ligated together; see p. 1470, materials and methods heading, where T4-polynucleotide ligase was used and where T4 kinase can act as a blunt or sticky ligase).

With regard to claim 14, Sgaramella teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA (Figure 1).

With regard to claim 15, Sgaramella teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA using a second complementary strand (p. 1469, lines 3-8, where icosanucleotide formed between segments 1 and 4 were used as a template for joining segments 2 and 3, see Figure 1; see also p. 1470, materials and methods, where T4polynucleotide ligase were used).

With regard to claim 16, Sgaramella teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA using a second complementary strand as a template (p. 1469, lines 3-8, where icosanucleotide formed between segments 1 and 4 were used as a template for joining segments 2 and 3, see Figure 1; see also p. 1470, materials and methods, where T4-polynucleotide ligase were used).

9. Claims 21, 25, 32, 34-35, 42, 46, 53 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Khorana (1979, Science, vol. 203, no. 4381, pp. 10), and

614-625). Khorana teaches total synthesis of a specific DNA sequence through hybridization of short oligonucleotides prior to kinase treatment and ligation (Abstract).

With regard to claim 21, Khorana teaches a method of making very long, double stranded synthetic polynucleotides comprising the steps of:

- a) providing a multiplicity of oligonucleotides (Figure 7; see also p. 616, col. 3, 'total synthesis' heading, lines 1-5, where 26 chemically synthesized segments were used), b) sequentially hybridizing said oligonucleotides to each other (Figure 7, see also Figure
- c) enzymatic ligating said oligonucleotides to provide a contiguous piece of PCR-ready DNA of predetermined sequence (Figure 7, see also p. 616, col. 1, bottom of page were overlapping sequences joined by ligase; see also Figure 10).

With regard to claim 25, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes a ligase (p. 617, col. 1, middle of page, where ligase is mentioned; also see Abstract).

With regard to claim 32, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes ligase joining two strands of DNA (Figure 10, where 'the carets indicate the sites where joining was accomplished by the use of polynucleotide ligase').

With regard to claim 34, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes sticky-end ligase joining two strands of DNA (see Figure 7 where overhanging ends at each end of the segments are ligated,

see Figure 10 where segments were joined where 'the carets indicate the sites were joining was accomplished by use of polynucleotide ligase').

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With regard to claim 35, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes ligase wherein said ligase joins two single-strands of DNA (see Figures 7 and 10, for example, note the ends of segments I and II, fragments labeled 5 and 7, where overhanging single stranded ends are joined in Figure 10).

With regard to claim 42, Khorana teaches a method of constructing very long. double-stranded synthetic polynucleotides comprising the steps of:

- a) providing a multiplicity of short single-stranded oligonucleotides (Figure 7; see also p. 616, col. 3, 'total synthesis' heading, lines 1-5, where 26 chemically synthesized segments were used),
- b) sequentially hybridizing short single-stranded oligonucleotides to each other (Figure 7 and Figure 10), and
- c) enzymatic ligating said short single-stranded oligonucleotides to provide a contiquous piece of PCR-ready double stranded DNA of predetermined sequence (Figure 7, see also p. 616, col. 1, bottom of page were overlapping sequences joined by ligase).

With regard to claim 46, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes a ligase (p. 617, col. 1, middle of page, where ligase is mentioned; also see Abstract).

With regard to claim 53, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes ligase joining two strands of DNA (Figure

10, where 'the carets indicate the sites where joining was accomplished by the use of polynucleotide ligase').

With regard to claim 55, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes sticky-end ligase joining two strands of DNA (Figure 10, where 'the carets indicate the sites where joining was accomplished by the use of polynucleotide ligase').

With regard to claim 56, Khorana teaches a method constructing polynucleotides wherein said step of enzymatic ligating utilizes ligase wherein said ligase joins two single-strands of DNA (see Figures 7 and 10, for example, note the ends of segments I and II, fragments labeled 5 and 7, where overhanging single stranded ends are joined in Figure 10).

10. Claims 1-9, 11-16, 19, 21-30, 32-37, 40, 42-51, 53-58 and 61 rejected under 35 U.S.C. 102(b) as being anticipated by Hunkapiller et al. (US Patent 5,942,609; August 1999). Hunkapiller teaches methods of assembly of polynucleotides on a solid support using steps of annealing, ligation and extension (Abstract, lines 1-3).

With regard to claim 1, Hunkapiller teaches a method of constructing polynucleotides, comprising the steps of: ligating the strands of DNA using a complementary sequence as a template and a ligase (Figure 1b-c, see also col. 3, line 36 to col. 4, line 50; col. 12, lines 1-40 where the bridging oligonucleotide is complementary to the immobilized oligonucleotide, anneals to create a double-stranded fragment with an overhang and an assembly oligonucleotide complementary to the

overhang of the non-immobilized oligonucleotide to create a second double-stranded fragment and where "additional assembly and bridging oligonucleotides are introduced to form nicks in the immobilized strand and gaps in the non-immobilized strand. The nick sites are ligated in the immobilized strand by DNA ligase or chemical means.").

With regard to claim 21, Hunkapiller teaches a method of making very long, double-stranded synthetic polynucleotides comprising the steps of:

- a) providing a multiplicity of oligonucleotides (Figure 4e, see also col. 5, line 66 to col. 6, lines 1-6, where the steps of annealing and ligating are repeated n times),
- b) sequentially hybridizing said oligonucleotides to each other (col. 5, lines 66-67, where sequential annealing to an immobilized oligo is described; see also col. 12, lines 1-40), and
- c) enzymatic ligating said oligonucleotides to provide a contiguous piece of PCR-ready DNA of predetermined sequence (col. 6, lines 1-6).

With regard to claim 42, Hunkapiller teaches a method of constructing very long, double-stranded synthetic polynucleotides comprising the steps of:

- a) providing a multiplicity of short single-stranded oligonucleotides (Figure 4e, see also col. 5, line 66 to col. 6, lines 1-6, where the steps of annealing and ligating are repeated n times),
- b) sequentially hybridizing short single-stranded oligonucleotides to each other (col. 5, lines 66-67, where sequential annealing to an immobilized oligo is described; see also col. 12, lines 1-40), and

c) enzymatic ligating said short single-stranded oligonucleotides to provide a contiguous piece of PCR-ready double stranded DNA of predetermined sequence (col. 6, lines 1-6).

With regard to claims 2-3, 22-24 and 43-45, Hunkapiller teaches a method of constructing polynucleotides, comprising the steps of: ligating the strands of DNA using a complementary sequence as a template and a ligase (Figure 1b-c, see also col. 3, line 36 to col. 4, line 50; col. 12, lines 1-40 where the bridging oligonucleotide is complementary to the immobilized oligonucleotide, anneals to create a double-stranded fragment with an overhang and an assembly oligonucleotide complementary to the overhang of the non-immobilized oligonucleotide to create a second double-stranded fragment and where "additional assembly and bridging oligonucleotides are introduced to form nicks in the immobilized strand and gaps in the non-immobilized strand. The nick sites are ligated in the immobilized strand by DNA ligase or chemical means.").

With regard to claim 4, 25 and 46, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes a ligase (see col. 10, lines 1-45, specifically lines 14-33).

With regard to claim 5, 26 and 47, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes a linker (col. 9, lines 22-30; see also col. 7, lines 28-29, where a linker connects an oligonucleotide to a solid support).

With regard to claim 6, 27 and 48, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes ds-DNA (Figure 1c and 4c, where the site of ligation is surrounded by double-stranded DNA).

With regard to claim 7, 28 and 49, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes a surface with a template at said surface (Abstract; col. 3, lines 36-38; col. 7, lines 29-35; see also Figures 1-6).

With regard to claim 8, 29 and 50, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes a surface with a linker at said surface (col. 9, lines 22-30; see also col. 7, lines 28-29).

With regard to claim 9, 30 and 51, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes a surface with ds-DNA at said surface (Figure 1c and 4c, where the site of ligation is surrounded by double-stranded DNA).

With regard to claims 11, 14, 32, 35, 53 and 56, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase joining two strands of DNA (Figure 1b-c, see also col. 3, line 36 to col. 4, line 50) where the strands are single strands (see col. 7, lines 40-44, where overhangs are single stranded).

With regard to claim 12, 13, 33, 34, 54 and 55, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes blunt-end or stickend ligase joining two strands of DNA (see col. 10, lines 1-45, specifically lines 14-33, where T4 ligase can act as either a sticky or blunt ligase).

With regard to claim 15, 36 and 57, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA using a second complementary strand (Figure

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1b-c, see also col. 3, line 36 to col. 4, line 50; col. 12, lines 1-40, see detailed explanation above; see also col. 7, lines 40-44, where overhangs are single stranded).

With regard to claim 16, 37 and 58, Hunkapiller teaches a method of constructing polynucleotides wherein said step of ligating utilizes ligase wherein said ligase joins two single-strands of DNA using a second complementary strand as a template (Figure 1b-c, see also col. 3, line 36 to col. 4, line 50; col. 12, lines 1-40, see detailed explanation above; see also col. 7, lines 40-44, where overhangs are single stranded).

With regard to claim 19, 40 and 61, Hunkapiller teaches a method of constructing polynucleotides including repeatedly adding either single-stranded or double-stranded DNA to a growing piece of double-stranded DNA (Figure 1b-c, see also col. 3, line 36 to col. 4, line 50; col. 12, lines 1-40, see detailed explanation above; where single stranded bridging and annealing oligonucleotides are added to the growing ds-DNA as evidenced in Figures 1 and 4, for example).

### Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. Claims 20, 41 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunkapiller et al (US Patent 5,942,609; August 1999) in view of Gearing et al. (1985, Biochemistry International, vol. 10, no. 6, pp. 907-915). Hunkapiller teaches

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methods of assembly of polynucleotides on a solid support using steps of annealing, ligation and extension (Abstract, lines 1-3).

Hunkapiller teaches the limitations of claims 19, 40 and 61 as recited in the 102 rejection stated above, where the method includes repeatedly adding either single-stranded or double-stranded DNA to a growing piece of double-stranded DNA.

Hunkapiller does not teach the combination and assembly directed by a computer program.

Gearing teaches the use of a computer program to direct the oligonucleotide sequence assembly and combination of polynucleotides in gene assembly (ENRGFIT, p. 908 'parameters for oligonucleotide design' heading).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the use of a computer program to direct the combination and assembly of the synethesized oligonucleotides. As taught by Gearing, the computer program was used for "maximization of interactions necessary to construct the gene and the minimization of irrelevant cross-hybridization of oligonucleotides. (p. 912, 'rationale for oligonucleotide design' heading)." The use of the computer program decreased the number of steps needed for synthesis to a single ligation reaction and therefore provided increased speed of experimental design and faster decisions with regards to specific fragments for synthesis and order of hybridization and assembly, benefits which would be useful when applying the method of Hunkapiller to a complex sequence or to the synthesis of entire genes or regions of a chromosome.

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### Allowable Subject Matter

13. Claims 10, 17-18, 31, 38-40, 52 and 59-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Claims 1-9, 11-16, 19-30, 32-37, 41-51 and 53-58 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Slephanie K. Munt

JEFFREY FREDMAN PRIMARY EXAMINEF